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EXAMINER

ECKMAN, MICHELLE

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/594,357 | <b>Applicant(s)</b><br>MCLEOD ET AL. |  |
|                              | <b>Examiner</b><br>MICHELLE ECKMAN   | <b>Art Unit</b><br>3733              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 2,7,15,21 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-14,16-20,22,24-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 19 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,093,205 in view of Ferree (US 6,419,704 B1). Claim 1 of the patent discloses: A disc prosthesis comprising a block of an elastomeric or visco-elastic material which is encapsulated by a textile fabric and in which a flange, suitable for attachment to vertebral bodies, is provided as a fabric continuation of the encapsulating fabric.

Claim 19 of the patent fails to disclose the additional core being encapsulated by an additional inner fabric component.

Ferree discloses using an additional layer of fabric to encase the core (see lines 22-30 of column 8).

The difference between claim 19 of the application and claim 1 of the patent lies in the fact that the application claim merely adds features absent from the patent claim. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the core in claim 19 of the patent with an additional layer of fabric in

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order to increase the strength or longevity of the core (see Ferree, lines 3-12 of column 3).

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the core made of multiple components each within its own inner component must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 3, 6, 8-14, 16-18 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Dickman (US 7,066,960 B1, hereinafter "Dickman"). Dickman shows:

Regarding claim 1, a disc prosthesis comprising: a core (see annotated Fig. 5 below), the core being of elastomeric material (see lines 60-65 of column 7, see also lines 55-67 of column 8); an inner component encapsulating the core, the inner component being of fabric (see lines 55-67 of column 8, see also annotated Fig. 5 below) and providing a smooth inner contact surface for the core (the examiner notes that collagen fabric would provide a smooth surface), an outer component surrounding the inner component, the outer component being of fabric (see lines 55-67 of column 8, see also annotated Fig. 5 below); wherein movement between the inner and outer components is facilitated in preference to movement between the inner component and core (see page 33 of applicant's specification, the examiner notes that the outer component against the vertebral bodies is separate of the inner component that

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surrounds the core, therefore it should reduce the micro-motion between the core and the inner component).

Regarding claim 3, wherein the core is a single elastomeric component (see annotated Fig. 5 below).

Regarding claim 6, wherein at least one of in which the top surface and bottom surface of the core is at least one of octagonal, hexagonal, round, and elliptic (see annotated Fig. 4 below, the examiner notes that the top surface is round).

Regarding claim 8, wherein in which any movement, particularly sliding movement, within the disc is greater between the outer component and inner component than between the inner component and core (see page 33 of applicant's specification, the examiner notes that the outer component against the vertebral bodies is separate of the inner component that surrounds the core, therefore it should reduce the micro-motion between the core and the inner component).

Regarding claim 9, wherein in which the inner component is at least one of configured to and formed of one or more materials intended to promote tissue growth (see lines 60-65 of column 8, the examiner notes that the fabric can be bioincorporable to promote tissue growth).

Regarding claim 10, wherein in which one or more materials used in the inner component are bio-absorbable (see lines 60-65 of column 8, the examiner notes that collagen would bio-absorb over time).

Regarding claim 11, wherein the smooth inner contact surface provides in which uniform contact between the inner surface of the inner component and the core (see

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lines 60-65 of column 8, the examiner notes that collagen fabric would provide a smooth inner contact surface and since the core is completely encapsulated there would be uniform contact).

Regarding claim 12, wherein a top wall of the inner component is connected to a side wall and hence to a bottom wall, with one or more further side walls being connected to at least one of the top wall, side wall, and/or bottom wall (see annotated Fig. 5 below).

Regarding claim 13, wherein in which the inner component is formed from an element including a side wall connected on one edge to a top wall and connected on an opposing edge to a bottom wall, the side wall being connected on one side edge to one other side wall and the side wall being connected on the other side edge to one or more other walls (see annotated Fig. 5 below, see also annotated Fig. 4 below, the examiner notes that there would be rounded edges connecting each of the sides of the inner component).

Regarding claim 14, wherein in which the side walls of the inner component are contacted additional elements, provided by a continuous band extending around the side of the inner component (see annotated Fig. 4 below, that the side wall connected by rounded edges form a continuous band).

Regarding claim 16, wherein in which the outer component is at least one of configured and formed of one or more materials intended to promote tissue growth, particularly tissue ingrowth at least one of through the outer component, between the inner component and the core through the inner component (see lines 55-67 of column



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8, see also lines 1-20 of column 9, the examiner notes that the outer component is bioincorporable to promote tissue ingrowth).

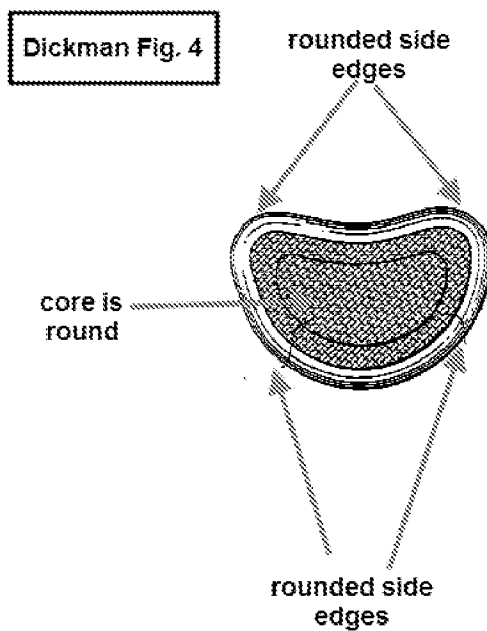
Regarding claim 17, wherein in which one or more materials used in the outer component are bio-absorbable (see lines 55-67 of column 8, see also lines 1-20 of column 9, the examiner notes that these bioincorporable materials would bioabsorb over time).

Regarding claim 18, wherein in which the outer component is formed from an element including a side wall connected on one edge to a top wall and connected on an opposing edge to a bottom wall, the side wall being connected on one side edge to two other side walls, the side wall being connected on the other side edge to two other side walls, a further side wall being connected to the opposite edge of the top wall or bottom wall to the edge to which the side wall linking the top wall and bottom wall is provided (see annotated Fig. 5 below).

Regarding claim 22, a method of performing spine surgery, comprising: providing a disc prosthesis, the disc prosthesis including a core formed of elastomeric material (see lines 60-65 of column 7, see also lines 55-67 of column 8), a fabric inner component encapsulating the core (see lines 55-67 of column 8, see also annotated Fig. 5 below) and providing a smooth inner contact surface for the core (the examiner notes that collagen fabric would provide a smooth surface), and an outer fabric component surrounding the inner component (see lines 55-67 of column 8, see also annotated Fig. 5 below), wherein movement between the inner and outer components is facilitated in preference to movement between the inner component and core (see page

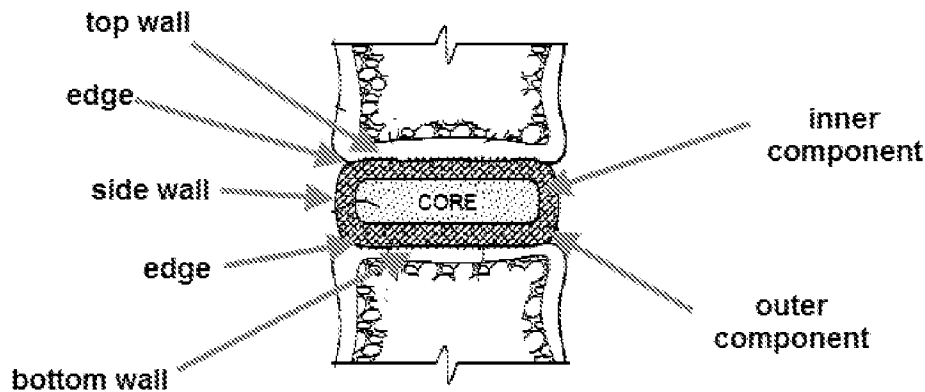
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33 of applicant's specification, the examiner notes that the outer component against the vertebral bodies is separate of the inner component that surrounds the core, therefore it should reduce the micro-motion between the core and the inner component); including, removing at least part of the natural disc in a spine; and implanting the inserting a disc prosthesis in the spine, into the area formerly occupied by the removed natural disc (see Fig. 5, the examiner notes that the implant shown in Fig. 5 has been inserted into the spine in an area formerly occupied by the removed disc).



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Dickman Fig. 5



### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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2. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dickman as applied to claim 1 above, and further in view of Bao et al. (US 5,192,326, hereinafter "Bao").

Dickman shows all of the features of the claimed invention as previously set forth above, except for the core being formed of multiple elastomeric components.

Bao teaches, regarding claim 4, wherein the core is formed of multiple elastomeric components, provided within its own inner component (see lines 9-15 of column 7).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the core in Dickman with the two-piece or beaded hydrogel core taught in Bao in order to facilitate implantation (see lines 9-15 of column 7).

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dickman as applied to claim 1 above, and further in view of Ferreira et al. (US 7,018,412 B2, hereinafter "Ferreira").

Dickman shows all of the features of the claimed invention as previously set forth above, except for the planar surfaces of the core being non parallel.

Ferreira shows, regarding claim 5, wherein in which the core provides a planar top surface and planar lower surface, the top and bottom surfaces not being parallel to one another, the separation of the top and bottom surfaces increasing from one side of the core to the other (see Fig. 5).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the planar surfaces of the core in Dickman to be nonparallel like

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the planar surfaces in Ferreira in order to accommodate for natural spinal lordosis (see lines 24-39 of column 5).

4. Claims 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickman Fig. 5 as applied to claims 1, 18, and 22 above, and further in view of Dickman Fig. 6.

Dickman shows all of the claimed features as previously set forth above in Fig. 5, except the flanges on the outer component.

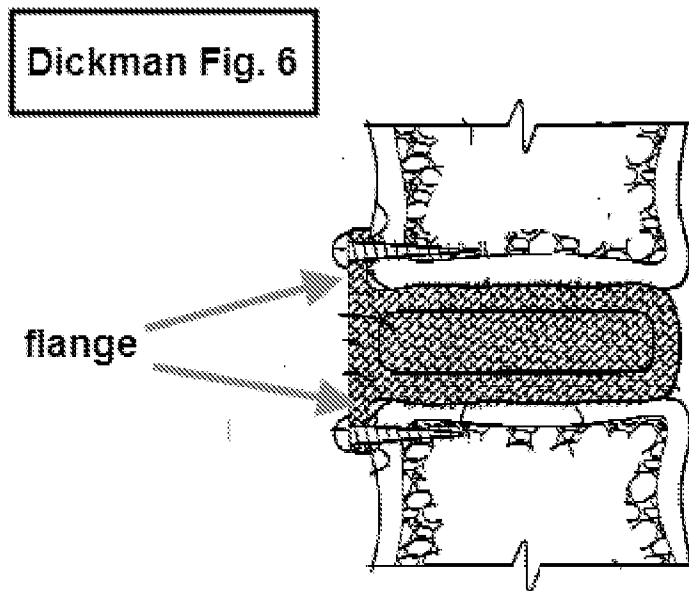
Dickman shows, regarding claim 19, wherein in which one or more edges of at least one of the top wall and/or the bottom wall of the outer component are provided with flanges, the flanges providing anchor locations for attaching the outer component to one or more vertebrae (see annotated Fig. 6 below).

Dickman further shows, regarding claim 25, wherein the disc prosthesis includes an outer component provided with flanges, the flanges providing anchor locations for attaching the outer component to one or more vertebrae (see annotated Fig. 6 below).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the outer component in Dickman Fig. 5 with the flanges shown in Dickman Fig. 6 to enhance fixation to the vertebrae and provide additional spinal

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stability (see 20-67 of column 9).



5. Claims 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickman in view of Wagner et al. (US 5,306,309, hereinafter "Wagner").

Dickman shows, regarding claim 20, a prostheses including a core formed of elastomeric material, the core being provided within an inner fabric component encapsulating the core and providing a smooth inner contact surface for the core, the and an outer fabric component surrounding the inner component, wherein movement between the inner and outer components is facilitated in preference to movement between the inner component and core (see lines 55-65 of column 8, see also Fig. 5).

Dickman fails to show a kit. Wagner shows a kit for use in providing a disc prosthesis, the kit including a series of different sized prostheses.

It would have been obvious to one having ordinary skill in the art at the time of invention to provide a kit with different sized prosthesis in order to decrease the duration of the procedure (see lines 3-43 of column 9).

Dickman further shows, regarding claim 24, wherein at least one of the prostheses includes an outer component provided with flanges, the flanges providing anchor locations for attaching the outer component to one or more vertebrae (see Fig. 6).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Trieu (US 2002/002644 A1) discloses an elastomeric core, encapsulated by a fabric inner jacket and surrounded by an outer shell, Stubstad et al. (US 3,867,728) discloses an elastic polymer core with tissue-ingrowthreceptive material on the surface, Baumgartner (US 5,171,280) discloses a coiled layered body made of fabric enveloped with an elastomer, Bergeron (US 7,905,922 B2) discloses an inner core encased in a first and second fabric.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE ECKMAN whose telephone number is (571)270-7051. The examiner can normally be reached on Monday - Friday, 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on (571)272-4719. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. E./

Examiner, Art Unit 3733

/EDUARDO C. ROBERT/

Supervisory Patent Examiner, Art Unit 3733